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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

NI *et al.*

Appl. No. 09/448, 868

Filed: November 24, 1999

For: **Death Domain Containing
Receptor-4 Antibodies**

Confirmation No. N/A

Art Unit: 1646

Examiner: Kaufman, C.

Atty. Docket: 1488.1300004/EKS/EJH/TAC

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**Reply To Restriction Requirement
and Requirement For Election Of Species** TECH CENTER 1600/2900

Commissioner for Patents
Washington, D.C. 20231

Sir:

In the Office Action dated **July 6, 2001**, the Examiner has made a restriction requirement, requiring an election of "species" within the previously elected group of antibodies and antibody fragments. In order to be fully responsive in the above-referenced patent application, Applicants hereby provisionally elect, with traverse, the subject matter of an antibody which specifically binds residues 1-468 of SEQ ID NO:2, including the polypeptide encoded by the human cDNA of ATCC Deposit No. 97853. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. Applicants reserve the right to file one or more divisional applications directed to non-elected subject matter should this restriction requirement be made final. In such case, Applicants retain the right to petition from this restriction requirement under 37 C.F.R. § 1.144.

In response to the Examiner's requirement that Applicants point out which claims correspond to the provisionally elected invention, Applicants have the following comments.

Since the provisional elected embodiment, *i.e.*, an antibody which specifically binds to amino acids 1-468 of SEQ ID NO:2 generally reads on, *i.e.*, is extensively overlapping in scope with an antibody which specifically binds to either amino acids 24-468, 24-238, 132-221, 35-92, 114-160, 169-240, 239-264, 265-468, 267-298, 330-364, 391-404, 418-465 and 379-422 of SEQ ID NO:2, Applicants respectfully point out that all the claims of Group I, *i.e.*, claims 22-42, 44-64, 66-73, and 75-82 are directed to the provisionally elected "species." Nevertheless, to the extent that the Examiner requests that Applicants list the claims particularly directed to the provisionally elected embodiment, Applicants point out that claims 22, 36-42, 44, and 63 are particularly directed to the provisionally elected embodiment.

Applicants respectfully traverse and request the withdrawal of the requirement for election of "species."

As a threshold matter, Applicants point out that M.P.E.P. § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (M.P.E.P. § 806.04 - § 806.04(i)) or distinct (M.P.E.P. § 806.05 - § 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the groups listed by the Examiner represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of both groups would entail a "serious burden." See M.P.E.P. § 803. In the present situation, no such showing has been made. Although the Examiner has asserted that antibodies that bind regions of the polypeptide of SEQ ID NO:2 from the following

group: amino acids 1-468 (including the polypeptide encoded by the human cDNA of ATCC Deposit No. 97853), 24-468, 24-238, 132-221, 35-92, 114-160, 169-240, 239-264, 265-468, 267-298, 330-364, 391-404, 418-465 and 379-422 are distinct, Applicants submit that a search of the antibody claims would be coextensive as a person skilled in the art would as a matter of routine use the claimed antibody to detect the disclosed polypeptide as described in Claims 22-42, 44-64, 66-73 and 75-82. Indeed, since a claim to an antibody that specifically binds a polypeptide comprising residues 1-468 of SEQ ID NO:2 (including the polypeptide encoded by the human cDNA of ATCC Deposit No. 97853) extensively overlaps in scope with claims to antibodies that specifically bind sequences from the group consisting of residues 24-468, 24-238, 132-221, 35-92, 114-160, 169-240, 239-264, 265-468, 267-298, 330-364, 391-404, 418-465 and 379-422 of SEQ ID NO:2 a search of all groups would entirely overlap. Thus the search and examination of all the antibody "species" in claims 22-42, 44-64, 66-73 and 75-82 would not entail a serious burden.

Applicants respectfully point out that the Examiner has not disclosed any statutory or regulatory basis for requiring the election of subsets of antibodies which bind to individual fragments of SEQ ID NO:2 recited in the previously elected Group I. Applicants respectfully point out that M.P.E.P. § 803.2 requires that "[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits.¹" Applicants submit that the "species" recited in the pending claims are sufficiently

¹Applicants note that pending claims 22-42, 44-64, 66-73 and 75-82 are not in Markush format, however, the Examiner's restriction requirement has been presented in Markush format, thus these remarks are directly applicable.

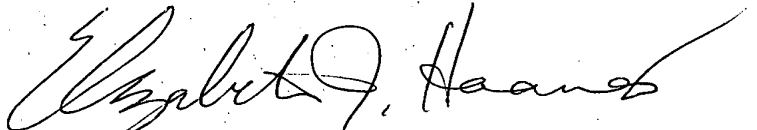
few in number and very closely related, as they are all different portions of *the same amino acid sequence*, so that a search of all of the members may be made without a serious burden, contrary to the Examiner's position.

Thus, Applicants respectfully request that the Restriction Requirement between the various "species" of antibodies be withdrawn so that the restricted subject matter can be examined together.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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